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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,351	03/19/2001	Sidney T. Smith	CRTS-5679 (1417A P 450)	3473

7590 05/05/2004

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EXAMINER
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PASCUA, JES F

ART UNIT	PAPER NUMBER
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3727

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/813,351	Applicant(s) SMITH ET AL.	
	Examiner Jes F. Pascua	Art Unit 3727	

-- *Th MAILING DATE of this communication appears on the cov r sheet with th correspondence address --*  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9,12-26,28-34 and 36-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9,12-26,28-34,36-44,50 and 51 is/are rejected.
- 7) ☒ Claim(s) 45-49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/19/04 has been entered.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 16, 24, 25, 36, 38, 39, 40, 41 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 6, 7 and 13 of U.S. Patent No. 6,659,132 in view of U.S. Patent No. 5,988,422 to Vallot. U.S. Patent No. 6,659,132 discloses the claimed device except for

the port closure being in communication with a container having a port. Vallot discloses that it is known in the art to provide a container with a port in communication with a port closure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the port closure of U.S. Patent No. 6,659,132 with the container and port of Vallot, in order to maintain the contents within the container in a sterile condition.

The microporous materials of claims 5 and 6 in U.S. Patent No. 6,659,132 inherently meet the structure of the present application's "barrier".

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-9, 12-15, 17-22, 28, 30, 31, 33, 34 and 50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,988,422 to Vallot (previously cited). See Figs. 1 and 2.

It is brought to applicant's attention that the angle defined between the longitudinal edges 19, 19' and the tapered edges 17, 17', 18, 18' in Fig. 2 of Vallot is shown as being in the range from about 135.01° to about 138°. Having met applicant's claimed range of angles in claim 17, the end panels of Vallot are inherently capable of

extending outwardly from the sleeve beyond an imaginary plane when in the unfolded position shown in Fig. 2.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 25, 26, 36, 37, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422.

Vallot '422 discloses the claimed invention, especially all of the materials used to construct the Vallot '422 container and its accessories being "capable of withstanding exposure to radiation and other known sterilization techniques." See column 3, lines 46-50. However, Vallot does not disclose the port closure (i.e. "stopper") in sterile communication with the port (i.e. "chimneys 8"). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stopper of Vallot '422 in sterile communication with the port of the container since it was known in the art to maintain the contents of bio-pharmaceutical containers in a sterile condition.

Regarding claims 43 and 44, the large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13 meet the structure of applicant's "vent closure" to the same degree as claimed.

Regarding claim 37, Vallot '422 discloses the claimed invention except for the communication member (i.e. a tube connecting to large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13) being about 6 ft. to about 30 ft. long. It would have been an obvious matter of design choice to use a 6 ft. to 30 ft. tube for the communication member of Vallot '422, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422.

Vallot '422 discloses the claimed invention except for the angle between the longitudinal edge 19, 19' and the tapered edge 17,17', 18, 18' being 136°. It would have been an obvious matter of design choice to make the angle between the longitudinal edge 19, 19' and the tapered edge 17,17', 18, 18' of Vallot '422 136°, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

9. Claims 29, 32 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422 and Sasaki et al.

Vallot '422 discloses the claimed device except for the top side of the container having a plurality of spaced-apart hanger connection locations. Sasaki et al. discloses that it is known in the art to provide a plurality of spaced-apart hanger connection locations 14. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the top side of the Vallot '422 container with the plurality of spaced-apart hanger connection locations of Sasaki et al., in order to permit the container to be suspended. Furthermore, the plurality of spaced-apart hanger connection locations 14 of Sasaki et al are shown as being positioned inward from an outer edge of the top side as claimed.

#### ***Allowable Subject Matter***

10. Claims 45-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


#### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-9, 12-26, 28-34 and 36-51 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jes F. Pascua whose telephone number is 703-308-1153. The examiner can normally be reached on Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lee W. Young can be reached on 703-308-2572. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jes F. Pascua  
Primary Examiner  
Art Unit 3727

JFP